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ORIGINAL ARTICLE

Balloon atrial septostomy: The oldest cardiac interventional procedure in Mansoura

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KEYWORDS

Balloon atrial septostomy;
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Abstract *Background:* Balloon atrial septostomy (BAS) was first described by Rashkind and Miller in 1966 and remains an important interventional procedure in the palliation of certain forms of congenital heart disease (CHD). Creating an atrial septa1 defect in patients with transposition of the great arteries (d-TGA) will enhance bidirectional mixing of the pulmonary and systemic venous blood, hence improving oxygen saturation. The aim of the work is to review and report our experience using balloon atrial septostomy in different CHD.

Method: We retrospectively reviewed the hospital records, echocardiographic and cardiac catheterization reports of patients subjected for BAS during the period from January 2001 till January 2010. One hundred and ninety two patients with CHD (78.5% d-TGA, 10% mitral atresia, 7.5% tricuspid atresia, and 4% hypoplastic left heart syndrome) underwent BAS. Their gestational age was 38.63 ± 1.48 weeks, postnatal age (median 3.5 days, range 1–54) and weight 3.08 ± 0.37 kg, 57.5% was male and 42.5% was female. All patients received PGE1 infusion before the procedure to maintain the ductal patency in a dose of 0.05–0.1 μg/kg/min.

Results: One hundred twenty two procedures (63.5%) were done in neonatal intensive care at bedside and 70 procedures (36.5%) in the catheterization laboratory. General anesthesia was used in 31.3% of patients whereas conscious sedation was used in 68.7% of patients. Femoral access in

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78% while umbilical access in 22%. Seven F sheath was used in 100% of case. The Miller catheter was used in 75% and a Z-5 septostomy catheter in 25% of cases. The diameter of the atrial communication increased from 2.75 ± 0.97 mm to 7.07 ± 0.79 mm ($p < 0.0001$). Oxygen saturations increased significantly from 65.38 ± 9.59% to 88.62 ± 3.13% ($p < 0.0001$). Mean pressure gradient for patients done in catheterization laboratory decreased from 4.1 ± 2.4 to 0.5 ± 1.1 mmHg ($p < 0.0001$). The number of septostomies required to achieve good results was 5.23 ± 1.20. No significant difference in oxygen saturation or the size of inter-atrial communication was observed between the two used balloons ($p = 0.6$).

Conclusion: BAS is safe and an effective palliative procedure for different CHD with good immediate results in our institution.

1. Introduction

Balloon atrial septostomy (BAS) remains an important interventional procedure in the palliation of certain forms of congenital heart disease (CHD) and considered by many to be the bread and butter of pediatric catheter intervention.[1] BAS was first described by Rashkind and Miller[2] in 1966 and remains an important interventional procedure in the palliation of certain forms of CHD. Typically it is performed in the cardiac catheterization laboratory under fluoroscopic guidance with hemodynamic monitoring. This procedure involves transport of a sick, cyanotic infant to the cardiac catheterization laboratory, often with some time delay from diagnosis to the start of BAS. Bedside BAS significantly reduces the cost to the patient without a change in efficacy and might be safer by obviating the need for transport of a sick infant to the cardiac catheterization laboratory.[3] The aim of the work is to review and evaluate our experience over the last 10 years.

2. Patients

2.1. Study population

From January 2001 till January 2010, we retrospectively reviewed the hospital records, echocardiographic and cardiac catheterization reports of patients with cyanotic congenital heart disease, who needed the presence of an adequate interatrial shunt to guarantee the survival until the moment when the palliative or definitive surgical treatment could be carried out. One hundred and ninety two patients with different CHD (d-TGA, mitral atresia, tricuspid atresia, and hypoplastic left heart syndrome) were admitted to the pediatric or neonatal intensive and underwent BAS. The diagnosis was confirmed in all patients by 2-dimensional echocardiography with Doppler and color flow Doppler. The equipment used for the echocardiographic assessment was (SONOS-5500, Hewlett Packard Andover, MA) with 12 MHz probe incorporating color flow, pulsed wave and continuous wave Doppler. Images were recorded on videotapes. Therapy for all patients was routinely begun with prostaglandin E1 in a dose of 0.05–0.1 μg/kg/min to maintain ductal patency. Their gestational age was 38.63 ± 1.48 weeks, postnatal age (median 3.5 days, range 1–54) and weight 3.08 ± 0.37 kg, 57.5% was male and 42.5% was female. The decision to perform the BAS was made based on the clinical findings of hypoxia, followed by the echocardiographic confirmation of restrictive atrial septal defect, characterized by the absence of visible communication or small-size communication, that is, < 2.0 mm or less than one forth of the total measurement of the interatrial septum measured in the subcostal position.

3. Methods

3.1. Septostomy catheters

Miller-Edwards™ Balloon Septostomy Catheter (Edwards Life sciences, Irvine, CA) is an extruded catheter with a single lumen connected to a Latex™ balloon at the tip. The Latex™ balloon is very compliant and, in order to be truly effective, it must be inflated with 5–6 cc of fluid to make the balloon even somewhat non-compliant. With a 4 or 6 cc volume the balloon reaches approximately 2 cm in diameter, and at that diameter the balloon does lose most of its compliance. Although not advertised, the burst volume of these balloons is 10–12 cc. The precautions and expiration date on these balloons must be strictly observed, as Latex™ deteriorates fairly rapidly when in light and/or with time. These balloons do not have a separate true lumen and must be manipulated and positioned visually using fluoroscopy or echo. They do come with a very fine stainless steel stylet which is useful, not only for deflecting the tip of the catheter, but also for clearing the very tiny lumen should it become clogged and prevent deflation of the balloon.[4] Z-5 septostomy catheter [NuMED, Inc., Hopkinton, NY]) has been designed for the neonate with CHD requiring

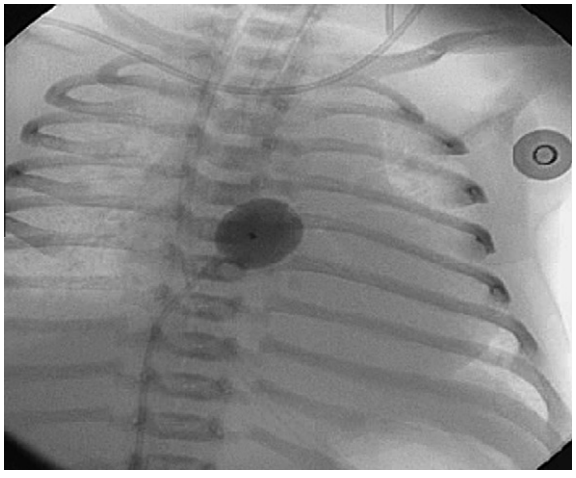

Figure 1 Contrast filled balloon in the left atrium and pulled against the atrial septum under fluroscopy.

septostomy. It is a 50-cm long dual lumen catheter with a 13.5 to 0.5-mm diameter noncompliant balloon made of polymeric nylon material with a maximal capacity of 2 cc at the distal end. It has an end-hole that will accommodate a 0.02 I″ guidewire. The inflated geometry of the balloon is a sphere. There is a radiopaque imaging band in the middle of the balloon for accurate positioning in the left atrium. The catheter tip is angled at 35″ to facilitate entry into the left atrium.[1]

4. Technique

The protocol we followed has been previously reported.[4,5] The procedure was done in the catheterization laboratory under fluoroscopic guidance (Fig. 1). In life-saving conditions and risky neonatal transport, the procedure was performed in the neonatal intensive care unit as a bedside procedure under transthoracic echocardiographic guidance; the standard subcostal view was mainly used to delineate the interatrial septum and to guide the balloon catheter from the right atrium to the left atrium via the patent foramen ovale (PFO) or tiny atrial septal defect (ASD) (Fig. 2).

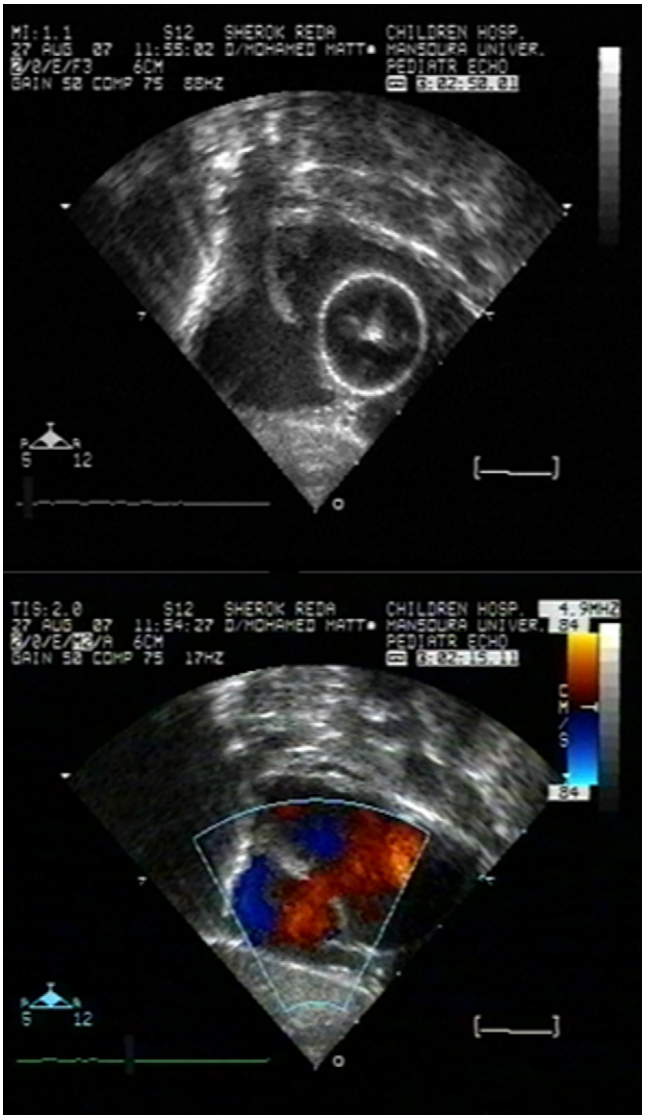

Figure 2 Subcostal view to guide the balloon through PFO and creat wide ASD.

1. Venous (umbilical/femoral) access is obtained with the appropriate size sheath.
2. A balloon septostomy catheter (the Miller catheter [Edwards-Baxter Healthcare Corporation, Santa Ana, CA] or the Z-5 septostomy catheter [NuMED, Inc., Hopkinton, NY]) is then advanced through the sheath up to the right atrium and through the atrial communication to the left atrium.
3. Appropriate positioning of the balloon at the atrial septum to avoid any potential complication is of crucial importance. Abnormal positions of the balloon such as: left atrial appendage or the right atrial appendage in patients with juxtaposed right atrial appendage, the left pulmonary veins, through the left atrioventricular (AV) valve to the left ventricle must be avoided.
4. The balloon is then inflated in the left atrium then pulled into the right atrium using a rapid and forceful jerk.
5. The forceful jerk/pull motion should be stopped at the right atrium inferior vena cava junction. The catheter should be pushed back to the mid right atrium then deflated as rapidly as possible.
6. The deflated catheter is advanced to the left atrium and the procedure is repeated until adequate atrial communication is achieved and no resistance is felt during passage of the inflated balloon across the defect.
7. At the end of the procedure the balloon is deflated and pulled outside the body.
8. The procedure was done under either general anesthesia or conscious sedation.

The success criterion of the procedure was the increase in the peripheral oxygen saturation, the increase in the atrial septal defect diameter $>1/3$ of the total septal diameter measured at the subcostal view or around 5 mm with ample border motility and clinical improvement. The transatrial gradient at the pulsed Doppler, both pre and post-procedure, was not considered a criterion of success, as it presented a wide interobserver variation related to the angle of insonation.

4.1. Statistical analysis

Data were statistically analyzed with the use of the Statistical Package for Social Science program (SPSS version 15.0 for windows, Chicago, IL). The descriptive statistical analysis of the quantitative variables was carried out by calculating the median, mean and standard deviations. Student's t test was used to compare the values of oxygen saturation and atrial septal defect diameter and mean interatrial pressure gradient before and after the procedure. Statistical significance was achieved when P was <0.05.

5. Results

One hundred and ninety two patients with CHD (78.5% d-TGA, 10% mitral atresia, 7.5% tricuspid atresia, and 4% hypoplastic left heart syndrome) underwent BAS (Fig. 3). One hundred twenty two procedures (63.5%) were done in neonatal intensive care unit at bedside and 70 procedures

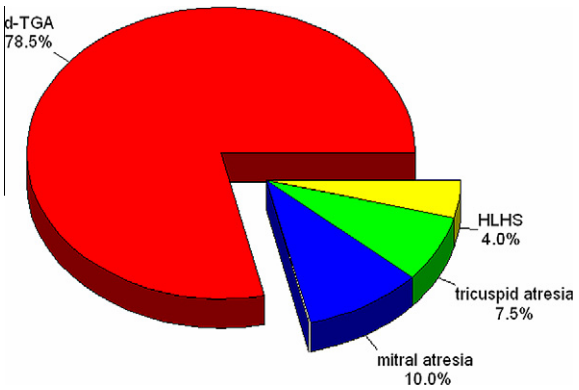

Figure 3 Types of complex congenital cyanotic heart diseases subjected for balloon septostomy.

(36.5%) in the catheterization laboratory. General anesthesia was used in 31.3% of the patients whereas conscious sedation was used in 67.7% of the patients. Femoral access was used in 78% of cases while umbilical access was used in 22% of cases. Seven F sheath was used in 100% of cases. The Miller catheter was used in 75% and a Z-5 septostomy catheter in 25% of cases. The diameter of the atrial communication increased from 2.75 ± 0.97 mm to 7.07 ± 0.79 mm ($p < 0.0001$). Oxygen saturations increased significantly from 65.38 ± 9.59% to 88.62 ± 3.13% ($p < 0.0001$). Mean pressure gradient for patients done in the catheterization laboratory decreased from 4.1 ± 2.4 to 0.5 ± 1.1 mmHg ($p < 0.0001$) (Table 1). The number of septostomies required to achieve good results was 5.23 ± 1.20. No significant difference in oxygen saturation or the size of inter-atrial communication was observed between the two used balloons ($p = 0.6$). Complications encountered were premature ectopic beats in 54% of cases, supraventricular tachycardia (SVT) in 8% of cases and venous thrombosis in 2% of cases. Cardiac perforation of left atrial appendage (LAA) occurred in one patient and managed surgically. Balloon rupture occurred in 7% of cases and all ruptured balloons were of Miller type, no embolization of balloon fragments was reported. There were no procedural deaths and five patients developed a sepsis-like picture after the procedure and died.

6. Discussion

Balloon atrial septostomy (BAS) was first described in 1966 by Rashkind and Miller[2] as palliation for patients with transposition of the great arteries to improve saturation. When introduced, the technique of BAS was the most important single factor influencing survival in patients with TGA. Creating a nonrestrictive atrial communication optimizes mixing at the atrial level, improving systemic arterial oxygen content and cardiac output as well as lowering the left atrial pressure. These beneficial effects often lead to a rapid stabilization of these neonates and improve their condition before they undergo a major neonatal operation.[6]

Table 1 Immediate effect of BAS.

	Pre-BAS	Post-BAS	*P*
Diameter of ASD (mm)	2.75 ± 0.97	7.07 ± 0.79	<0.0001
Oxygen saturation (%)	65.38 ± 0.59	88.62 ± 3.13	<0.0001
Mean pressure gradient (mm Hg)	4.1 ± 2.4	0.5 ± 1.1	<0.0001

ASD; Atrial septal defect.

BAS is a life-saving procedure for patients born with d-TGA. The use of prostaglandins, however, has reduced its need in patients with restrictive atrial septal defects with poor mixing of saturated atrial blood whose preductal saturations cannot be maintained in an acceptable range or in those whose surgery will be delayed for some reason.[7]

In the early era of the arterial switch operation when an emphasis was placed on the systemic left ventricular pressures, a 2-coronary system, and no semilunar valve or subvalve stenosis, cardiac catheterization was an integral part of the evaluation. In the recent era, cardiac surgeons have solved the technical problems, and the need for hemodynamic evaluation with direct pressure measurements has become less important. The use of echocardiography in diagnosing d-TGA is the standard of care and has been used for 15 years. The atrial septum can be easily evaluated by subcostal imaging, making it an ideal method for monitoring BAS.[8]

In fact, echocardiographic guidance is helpful for the balloon position in the left atrium[9] and BAS can be performed at the bedside if safe, reliable, vascular access can be obtained and catheter movement and position verified. All of these can be accomplished at the bedside using the umbilical vein or femoral vein and echocardiographic imaging of the catheter course and position within the heart because the catheter and wires used are echo dense as described before.[10,11]

We have shown that the use of transthoracic echocardiography and BAS at the bedside is safe and effective and accompanied by very little morbidity. Similar improvement in oxygen saturation obtained after BAS indicates equal efficacy at the bedside or in the catheterization laboratory. We tried to avoid the transport of the sick newborn to the catheterization laboratory reducing the delay from diagnosis to septostomy, moreover there is no radiation exposure and the result of the procedure can be verified as the procedure takes place. The limitations of transthoracic echo guidance of BAS include the possibility of poor echo window in an ill neonate on assisted ventilation and possible interference with maneuverability for either echocardiographer or catheter operator particularly when umbilical vein cannulation is performed. This makes an indication to do the procedure in the catheterization laboratory or under guidance of transesophageal echocardiography as previously described.[12]

We agree with Baker et al.[13] and Perry et al.[14] that full cardiac catheterization is not required for the initial diagnosis or assessment of neonates with d-TGA and BAS is best performed in the neonatal intensive care unit under 2D control. Although the concept made by Baker et al.[13] that cardiac catheterization remained an integral part of the evaluation of d-TGA in the early era of the arterial switch operation, patients still have unanswered critical questions after full echocardiographic evaluation.

In our study, bedside septostomy was markedly less expensive than its cardiac catheterization laboratory counterpart. Potential savings include reduced fees for transport, for use of the cardiac catheterization laboratory, and for personnel (including overtime for callbacks in the middle of the night), and reduced physician charges.

The study was limited by the retrospective nature of the review. Additionally, the spectrum of disease and underlying

pathophysiology varied widely with a complex interplay of factors effecting outcomes.

7. Conclusion

The balloon atrial septostomy using fluoroscopy or 2D-ECHO is an acknowledged technique in the palliative treatment of cyanotic CHD in hypoxemic neonates due to inadequate intracardiac mix. BAS is safe and effective palliative procedure for different CHD with good immediate results in our institution. BAS improves the hemodynamics in a variety of compromised circulations and is similarly effective in palliation until definitive surgery can be attempted.

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